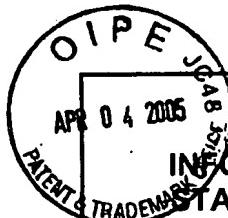


4/4/2005

Substitute PTO/SB/08A-8 (08-03)  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE.



Substitute for form 1449A/PTO  
(Modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

1

<b>Complete If Known</b>	
Application Number	10/734,631
Filing Date	December 11, 2003
First Named Inventor	Gallop
Art Unit	1614
Examiner Name	Not assigned

Attorney Docket Number 34471/US/3

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
UL	A1	4,285,987	08-21-1981	Ayer et al.	
UL	A2	6,833,140	12-21-2004	Cundy et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1					

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
UL	C1	LINHARDT, "Biodegradable Polymers for Controlled Release of Drugs," Chapter 2 of Controlled Release of Drugs, Rosoff (Ed.), pp. 53-95, VCH Publishers, 1989	
UL	C2	HOES et al., "The Application of Drug-Polymer Conjugates in ChemoTherapy," Chapter 3 of Drug Carrier Systems, Roerdink and Kroons (Ed.) pp. 57-109, John Wiley & Sons Ltd, 1989	

Examiner Signature		Date Considered	5/4/2005
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinda Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

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10/25/2004

Substitute PTO/SB/08A-B (08-03)  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE.

Substitute for form 1449A/PTO (Modified)				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Art Unit	1614
				Examiner Name	Not Assigned
Sheet	1	of	5	Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CL	A1	2,996,431	08-15-1961	Barry	
	A2	3,139,383	06-30-1964	Neville	
	A3	3,402,240	09-17-1968	Cain et al.	
	A4	3,811,444	05-21-1974	Heller et al	
	A5	3,916,899	11-04-1975	Theeuwes et al.	
	A6	3,845,770	11-05-1974	Theeuwes et al.	
	A7	3,916,899	11-04-1975	Theeuwes et al.	
	A8	3,962,414	06-08-1976	Michaels	
	A9	3,992,518	11-16-1976	Chien et al.	
	A10	4,024,175	05-17-1977	Satzinger et al.	
	A11	4,063,064	12-13-1977	Saunders et al.	
	A12	4,066,747	01-03-1978	Capozza	
	A13	4,070,347	01-24-1978	Schmitt	
	A14	4,079,038	03-14-1978	Choi et al.	
	A15	4,083,949	04-11-1978	Benedikt	
	A16	4,087,544	05-02-1978	Satzinger et al.	
	A17	4,088,864	05-09-1978	Theeuwes et al.	
	A18	4,093,709	06-06-1978	Choi et al.	
	A19	4,285,987	08-25-1981	Ayer et al.	
	A20	4,421,736	12-20-1983	Walters	
	A21	4,434,153	02-28-1984	Urquhart et al.	
	A22	4,721,613	01-26-1988	Urquhart et al.	
	A23	4,752,470	06-21-1988	Mehta	
	A24	4,820,523	04-11-1989	Shthohry et al.	

Examiner Signature

Date Considered

5/4/2007

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Substitute for form 1449A/PTO (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
Sheet	2	of	5	Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Art Unit	1614
				Examiner Name	Not Assigned
				Attorney Docket Number	
				34471/US/3/AMP/SKS (459258-00014)	

<b>'U.S. PATENT DOCUMENTS'</b>					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CL	A25	4,816,263	05-28-1989	Ayer <i>et al.</i>	
	A26	4,853,229	08-01-1989	Theeuwes	
	A27	5,084,479	01-28-1992	Woodruff	
	A28	5,563,175	10-08-1996	Silverman <i>et al.</i>	
	A29	6,001,876	12-14-1999	Singh	
	A30	6,020,370	02-01-2000	Horwell <i>et al.</i>	
	A31	6,024,977	02-15-2000	Yatvin <i>et al.</i>	
	A32	6,028,214	02-22-2000	Silverman <i>et al.</i>	
	A33	6,103,932	08-15-2000	Horwell <i>et al.</i>	
	A34	6,117,906	09-12-2000	Silverman <i>et al.</i>	
	A35	6,171,615	01-09-2001	Roussin <i>et al.</i>	
	A36	6,375,987	04-23-2002	Farah <i>et al.</i>	
	A37	6,379,700	04-30-2002	Joachim <i>et al.</i>	
	A38	10/710,127	06-11-2002	Gundy <i>et al.</i>	
✓	A39	10/171,485	06-11-2002	Gallop <i>et al.</i>	
✓	A40	10/167,197	06-11-2002	Gallop <i>et al.</i>	

Examiner Signature	<i>Mark Gallop</i>	Date Considered	11/14/2002
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Substitute for form 1449A/PTO (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
Sheet	3	of	5	Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Art Unit	1614
				Examiner Name	Not Assigned
				Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
UL	B1	EP 1,178,034 A1	02-05-2002	Warner Lambert Co.	
UL	B2	EP 1,201,240 A2	05-02-2002	Warner Lambert Co.	
UL	B3	GB 2,362,646 A	11-28-2001	Warner Lambert Co.	
UL	B4	WO 92/09560 A1	06-11-1992	Univ. Northwestern	
UL	B5	WO 93/23383 A1	11-25-1993	Univ. Northwestern	
UL	B6	WO 97/29101 A1	08-14-1997	Warner Lambert Co.	
	B7	WO 97/33858 A1	09-18-1997	Warner Lambert Co.	
	B8	WO 97/33859 A1	09-18-1997	Warner Lambert Co.	
	B9	WO 98/17627 A1	04-30-1998	Warner Lambert Co.	
	B10	WO 99/08671 A1	02-25-1999	Warner Lambert Co.	
	B11	WO 99/21824 A1	05-06-1999	Warner Lambert Co.	
	B12	WO 99/31057 A1	06-24-1999	Warner Lambert Co.	
	B13	WO 99/31074 A2/A3	06-24-1999	Warner Lambert Co.	
	B14	WO 99/31075 A1	06-24-1999	Warner Lambert Co.	
	B15	WO 99/37296 A1	07-29-1999	Warner Lambert Co.	
	B16	WO 99/61424 A1	12-02-1999	Warner Lambert Co.	
	B17	WO 00/15611 A1	03-23-2000	Warner Lambert Co.	
	B18	WO 00/23067 A1	0427-2000	Warner Lambert Co.	
	B19	WO 00/31020 A1	06-02-2000	Warner Lambert Co.	
	B20	WO 00/50027 A1	08-31-2000	Warner Lambert Co.	
	B21	WO 01/90052 A1	11-29-2001	Warner Lambert Co.	
↓	B22	WO 02/00209 A2/A3	01-03-2002	Warner Lambert Co.	
↓	B23	WO 02/085839 A1	10-31-2002	Warner Lambert Co.	

Examiner Signature	<i>Chet Palen Jr</i>	Date Considered	5/4/2007
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\*Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

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Sheet	4	of	5	Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Group Art Unit	1614
				Examiner Name	Not Assigned
				Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document Country Code* Number* Kind Code* (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
WL	B24	WO 02/28881 A1	04-11-2002	XenoPort, Inc.		
	B25	WO 02/28883 A1	05-11-2002	XenoPort, Inc.		
	B26	WO 02/28411 A1	04-11-2002	XenoPort, Inc.		
	B27	WO 02/32376 A1	04-25-2002	XenoPort, Inc.		
	B28	WO 02/42414 A2/A3	05-30-2002	XenoPort, Inc.		
✓	B29	WO 02/090318 A1	11-14-2002	Warner Lambert Co.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T*
WL	C1	Alderman, "A Review of Cellulose Ethers in Hydrophilic Matrices or Oral controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. &amp; Prod. Mfr.</i> 1984, 5(3) 1-9.	
	C2	Bamba <i>et al.</i> , "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> 1979, 2, 307.	
	C3	Coleman <i>et al.</i> , "Polymer Review: A Practical Guide to Polymer Miscibility," <i>Polymers</i> 1990, 31, 1187-1231.	
	C4	During <i>et al.</i> , "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," 1989, <i>Ann. Neurol.</i> 25:351.	
	C5	Fincher, "Particle Size of Drugs and Its Relationship to Absorption and Activity," <i>J. Pharm. Sci.</i> 1968, 57, 1825-1835.	
	C6	Goodson, "Medical Applications of Controlled Release," vol. 2, pp. 115-138 (1984).	
	C7	Hoes <i>et al.</i> , "The Application of Drug-Polymer Conjugates in Chemotherapy," <i>Drug Carrier Systems</i> 1989, 9, 57-110.	
	C8	Howard <i>et al.</i> , "Intracerebral drug delivery in rats with lesion-induced memory deficits," <i>J. Neurosurg.</i> 1989 71(1):105-112.	
	C9	Langer <i>et al.</i> , "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J Macromol. Sci. Rev. Macromol Chem.</i> 1983, 23:61.	
	C10	Langer, "New Method of Drug Delivery," 1990, <i>Science</i> 249:1527-1533.	
	C11	Leong <i>et al.</i> , "Polymeric Controlled Drug Delivery," <i>Adv. Drug Delivery Rev.</i> 1987, 1, 199-233.	
✓	C12	Levy <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> 1985 228: 190.	

Examiner Signature	<i>Mark Malen</i>	Date Considered	5/3/2007
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet	5	of	5	Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Group Art Unit	1614
				Examiner Name	Not Assigned
				Attorney Docket Number	
				34471/US/3/AMP/SKS (459258-00014)	

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Citeq No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T#
ML	C13	Lu, "Dimensionless Presentation for Drug Release From a Coated Pure Drug Bead: 2 Experiment," <i>Int. J. Pharm.</i> , 1994, 112, 117-124.	
	C14	Peto <i>et al.</i> , "The TD50: a proposed general convention for the numerical description of the carcinogenic potency of chemicals in chronic-exposure animal experiments," <i>Environmental Health Perspectives</i> 1984, 58, 1-8.	
	C15	Saudek <i>et al.</i> , "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 1989, 321: 574.	
	C16	Sefton, "Implantable Pumps," <i>CRC Crit Rev Biomed. Eng.</i> 1987, 14:201.	
	C17	Verma <i>et al.</i> , "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 2000, 26:695-708.	

Examiner Signature	<i>the H. Haleway</i>	Date Considered	T/3/2007
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